

# Human Research Report<sup>TM</sup>

PROTECTING RESEARCH SUBJECTS AND RESEARCHERS

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## IRBs, the “Principle of Justice,” and Public Mistrust of Science During COVID

Although this article focuses on IRBs and the “Principle of Justice,” its intent is broader. As we will see, **IRBs may have a crucial role to play in countering public mistrust of science** and the refusal to vaccinate against COVID. But first ...

The ever-influential Secretary’s Advisory Committee on Human Research Protections (SACHRP) has issued a new set of recommendations for IRBs. The relevant document is titled “Consideration of the Principle of Justice 45 CFR part 46.”

We present here core segments of this new advisory and we will include more related details in future installments of our usual “IRB Recommendations by the SACHRP” feature.

“Injustice has no place in human subjects research and undermines public trust in science.<sup>1</sup>

[FN #1: ... SACHRP represents the scientific and academic establishment, and inherits that enterprise’s assumptions and biases. Justice in the practice of research on human subjects cannot be fully realized without trying to make these assumptions and biases explicit ....]” (SACHRP letter to HHS Secretary Xavier Becerra, J.D., July 22, p. 1; on the Web at <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-consideration-of-the-principle-of-justice-45-cfr-46.html>).

### Current Distrust of Science In COVID Pandemic

“[There are several terms, in particular, that we have used that may carry unintended meanings that are contrary to the intent of our recommendations.

Science -- when we write about science, we are talking about systematic learning from observation or experi-

ment. We are not talking about the academic, government[,] and commercial entities that embody institutional science.

We mean science as a method that recognizes that truth is best approximated empirically, and that we must not accept

**NOTE #1:** Quoted materials in this newsletter appear exactly as originally published in source documents, including any misspellings, grammatical errors, missing words, etc. However, we will on occasion insert words or edit text/formatting in brackets [ ] to make the material easier to read, or to add an underline emphasis.

**NOTE #2:** Emphases are added to articles by HRR by underlining or adding **bold/italics** to selected text, unless stated otherwise.

**NOTE #3:** Articles To Be Continued in subsequent issues are marked at the end of the article with {TBC}.

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the truth of our perceptions or beliefs without testing.]

One consequence of injustice, whether it manifests as inappropriate exclusion from participation or as exploitation of ‘populations of convenience,’ is the belief that human subjects research serves the interests of the privileged and powerful and therefore perpetuates economic, racial, religious, sexual, gender, and cultural biases.

The history of research on human subjects reflects numerous examples of the relationship between blindness to, or disregard of, issues of justice and consequent justified mistrust.

Most recently, the ongoing disparate economic and public health impacts of the COVID-19 pandemic, including issues related to vaccine equity and hesitancy, illustrate some of the sources and consequences of distrust in science and its social goals” (ibid).

### Potential Vital Role of Local IRBs

“Researchers and many others recognize human subjects research as a primary human activity dedicated to objectivity<sup>2</sup> and empiricism; however, it continues to be marred by unjust policies, practices, beliefs, and systems of power.

[FN #2: Objectivity -- objectivity and science are inseparable, but objectivity is aspirational. As people, we can only try to distance ourselves from our assumptions and beliefs, but true objectivity is impossible.

There are two reactions to that impossibility -- we can declare objectivity unattainable and therefore without value, but such a reaction condemns us to knowingly embrace one set of assumptions as better than another, a strategy that cannot but lead to conflict and division.

Or we can keep trying to identify and eschew our assumptions to try to build a common understanding where the only assumptions come from our collective humanity.]

It is time to reconsider and reestablish justice as a core principle in biomedical and social-behavioral research, reflecting the reality that the science of people must be accountable to people to be legitimate ....” (ibid).

### Local IRBs Already Have Recognized Role

“Human Research Protection Programs (HRPPs) and Institutional Review Boards (IRBs) have a limited but important role to play, and the recommendations in this document are intended as a starting point from which to develop more detailed policies and practices to help ensure fair access<sup>3</sup> to opportunities for research participation and reasonable assurance that the potential benefits from research are available and meaningfully applicable to all.

[FN #3: ... it is a core ethical tenet that research participation must be voluntary. Thus, opportunities must be available, but individuals must also have reason to participate.

Our recommendations largely address access, which is a necessary prerequisite, but articulating the goals of research in a way that is compelling to historically excluded communities is likely to require time and the rebuilding of trust, which will only happen through practice.]” (pp. 1-2).

In HRR’s opinion, continued communications from individual national spokespersons citing numbing numbers will do nothing whatever to change public mistrust of science into trust.

There’s an old saying that “all politics are local.” Changing public mistrust of science to at least a grudging trust must come from local sources too ... like from thousands of local IRBs and similar local “neighbors” -- not from national spokespersons, no matter how well-intentioned.

Now may be the best time for local IRB members to speak up for science, protect individual rights as they already have for decades, and thereby save lives by encouraging vaccinations against COVID-19.

The tens of thousands of local IRB members throughout the U.S. would thus expand their legacy of protecting individual rights while still supporting science more than ever before. © {TBC}

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